

ANIMAL AND PLANT HEALTH INSPECTION SERVICE **VETERINARY SERVICES**

Protecting U.S. Agriculture From Bioterrorism

APHIS and CDC work together to protect against bioterrorism by overseeing the possession, use, and transfer of select agents.

The U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) works to ensure the continued health, welfare, and value of our Nation's agriculture and natural resources. As part of this safeguarding mission, we help protect U.S. animal and plant health by overseeing the possession, use, and transfer of potentially damaging biological agents and toxins, which we refer to as "select agents."

APHIS' Agriculture Select Agent Services (AgSAS) carries out this work in our agency's security and bioterrorism preparedness efforts. Along with the Division of Select Agents and Toxins (DSAT), a parallel program through the U.S. Department of Health and Human Services' Centers for Disease Control and Prevention (CDC), we make up the Federal Select Agent Program (FSAP). AgSAS also regulates the import and interstate transport of other infectious organisms and agents (non-select agents) that can carry and pass on animal disease.



Federal Select Agent Program

AgSAS oversees governmental, academic, and commercial sector organizations that possess, use, or transfer select agents that could pose a severe threat to animal and plant health or animal and plant products. DSAT covers select agents that could pose a severe threat to public health and safety. Select agents that threaten both public and animal health (such as anthrax) or can be passed from animals to people are regulated by both AgSAS and DSAT.









Inspections

Any organizations that want to possess or use a select agent must be inspected by FSAP to make sure they comply with all select agent regulatory requirements. During these in-depth assessments, inspectors:

- · confirm the facility has appropriate safety and security measures in place to deter the theft, loss, or release of select agents;
- verify that laboratory workers are adequately trained to work safely with the select agents; and
- ensure that the facility maintains accurate records.

After a review of the facility's application and a successful inspection, the facility is registered with FSAP. It must then continue to pass all compliance inspections to maintain its registration. This includes an announced renewal inspection every 3 years, as well as an annual unannounced compliance inspection (conducted by AgSAS) in between the 3-year renewal inspection cycle. Other inspections may be required if an amendment to the registration is submitted for adding new laboratories, buildings, and/or select agents of a higher risk.

Guidance

FSAP provides guidance and support to help regulated groups and companies understand and meet the select agent requirements. Up-todate information and resources can be found at www.selectagents.gov. These include: guidance documents, checklists based on regulations and national standards, inspection videos, and an email link for questions or requests.

FSAP also hosts annual workshops to help program participants understand their legal responsibilities for complying with the select agent regulations.

Working With Federal Partners

FSAP works closely with the U.S. Department of Justice to identify people who cannot access regulated select agents, based on the restrictions under Title 42, section 262a and Title 7, section 8401 of the *United States Code* (42 USC 262a and 7 USC 8401). To ensure the safe handling and use of select agents, FSAP also joins forces with numerous other Federal partners:

- Infrastructure Protection Program, within the U.S. Department of Homeland Security (DHS), identifies potential vulnerabilities and threats to registered entities in the United States.
- U.S. Department of Transportation (DOT)
 determines whether entities transferring select
 agents are complying with DOT regulations.
- Federal Bureau of Investigation conducts criminal investigations on the potential misuse or illegal acquisition of select agents.
- DHS' Science and Technology Directorate
 provides compliance support and oversight
 for registered DHS entities and select agent
 activities conducted or sponsored by DHS.
- U.S. Department of the Army Inspector General's Technical Inspections Division conducts general, compliance-oriented inspections of chemical, biological, radiological, nuclear, and other technical operations.
- U.S. Department of Veterans Affairs' (VA)
 Office of Research Oversight handles all matters of VA research compliance and assurance, including protection of human research subjects; laboratory animal welfare; research safety, laboratory security, information security, and misconduct; and governmentwide debarment for research impropriety.

Organism and Vectors Import/ Transport Permit Program

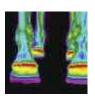
AgSAS' Organism and Vector (OV) Import/Transport Permit Program regulates the import and interstate transport of infectious biological agents, infectious substances, and organisms that can carry and pass on animal disease. To issue a permit, OV reviews the permit application and may inspect the group or company's facilities to make sure they can safely handle these materials. Importation permits are issued only to the importer, who must be located in the United States. To be successfully inspected, cleared, and released at U.S. ports of entry by DHS' Customs and Border Protection, these imported items must be accompanied by valid USDA import permits and have proper packaging and labeling.

OV also collaborates with CDC's Import Permit Program, which is charged with preventing the introduction, transmission, or spread of communicable diseases from foreign countries into the United States.









To learn more, go to or contact:

www.selectagents.gov

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